premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5580 Oxygen mask.

(a) *Identification.* An oxygen mask is a device placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5590 Scavenging mask.

(a) *Identification.* A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5600 Venturi mask.

(a) *Identification.* A venturi mask is a device containing an air-oxygen mixing mechanism that dilutes 100 percent oxygen to a predetermined concentration and delivers the mixed gases to a patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5610 Membrane lung for long-term pulmonary support.

(a) *Identification.* A membrane lung for long-term pulmonary support is a device used to provide to a patient extracorporeal blood oxygenation for longer than 24 hours.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987]

§ 868.5620 Breathing mouthpiece.

(a) *Identification.* A breathing mouthpiece is a rigid device that is inserted into a patient's mouth and that connects with diagnostic or therapeutic respiratory devices.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5630 Nebulizer.

(a) *Identification.* A nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

(a) *Identification.* A medicinal nonventilatory nebulizer (atomizer) is a device that is intended to spray liquid medication in aerosol form into the air that a patient will breathe.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5650 Esophageal obturator.

(a) *Identification.* An esophageal obturator is a device inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure

ventilation through the trachea. The device consists of a closed-end semirigid esophageal tube that is attached to a face mask.

(b) *Classification.* Class II (performance standards).

§ 868.5655 Portable liquid oxygen unit.

(a) *Identification.* A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is intended to supplement gases to be inhaled by a patient, is sometimes accompanied by tubing and an oxygen mask. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.

(b) *Classification.* Class II (performance standards).

§ 868.5665 Powered percussor.

(a) *Identification.* A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.

(b) *Classification.* Class II (performance standards).

§ 868.5675 Rebreathing device.

(a) *Identification.* A rebreathing device is a device that enables a patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5690 Incentive spirometer.

(a) *Identification.* An incentive spirometer is a device that indicates a patient's breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation.

(b) *Classification.* Class II (performance standards).

§ 868.5700 Nonpowered oxygen tent.

(a) *Identification.* A nonpowered oxygen tent is a device that encloses a patient's head and upper body to contain oxygen delivered to the patient for breathing. This generic type of device includes infant oxygen hoods.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5710 Electrically powered oxygen tent.

(a) *Identification.* An electrically powered oxygen tent is a device that encloses a patient's head and, by means of an electrically powered unit, administers breathing oxygen and controls the temperature and humidity of the breathing gases. This generic type device includes the pediatric aerosol tent.

(b) *Classification.* Class II (performance standards).

§ 868.5720 Bronchial tube.

(a) *Identification.* A bronchial tube is a device used to differentially intubate a patient's bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.

(b) *Classification.* Class II (performance standards).

§ 868.5730 Tracheal tube.

(a) *Identification.* A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

(b) *Classification.* Class II (performance standards).

§ 868.5740 Tracheal/bronchial differential ventilation tube.

(a) *Identification.* A tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung of a patient for anesthesia or pulmonary function testing.

(b) *Classification.* Class II (performance standards).